DEVICES FOR PHYSIOLOGICAL FLUID SAMPLING AND METHODS OF USING THE SAME

INTRODUCTION

FIELD OF THE INVENTION

[0001] The field of this invention is physiological fluid sampling and more particularly devices and methods of use thereof for non-invasively determining suitable physiological fluid sampling sites.

BACKGROUND OF THE INVENTION

[0002] Analyte concentration characterization in physiological samples is of ever increasing importance to today's society. Such assays find use in a variety of application settings, including clinical laboratory testing, home testing, *etc.*, where the results of such testing play a prominent role in the diagnosis and management of a variety of disease conditions. Analytes of interest include glucose for diabetes management, cholesterol for monitoring cardiovascular conditions, and the like. In response to this growing importance of analyte concentration characterization, a variety of analyte concentration characterization protocols and devices for both clinical and home testing have been developed.

[0003] To determine the concentration of an analyte in a physiological sample, a physiological sample must first be obtained from a site suitable for the particular test to be performed on the sample. For example, certain tests require a specific volume of interstitial fluid as the sample and others require a specific volume of blood, blood derivatives and the like as the sample. As such, depending on the type of sample required by the test, a site which expresses the requisite volume of the particular sample type must first be located.

[0004] The current processes of physiological fluid sample collection have certain drawbacks. First and foremost, such processes or techniques are associated with a significant amount of pain. Furthermore, a patient may need to endure multiple skin-piercings in order to find one suitable sampling site or enough sites to collect the

requisite amount of sample. The pain associated with sample collection may have serious adverse consequences for those who require analyte characterizations to be performed, *e.g.*, analyte detection and/or concentration determinations. For instance, patients who require frequent analyte concentration determinations may not adhere to their requisite testing protocols due to this associated pain and it is not uncommon for patients who require frequent monitoring of an analyte to simply avoid monitoring the analyte of interest because of the pain involved in sample collection. With diabetics, for example, the failure to measure their glucose level on a prescribed basis results in a lack of information necessary to properly control the level of glucose. Uncontrolled glucose levels can be very dangerous and even life threatening.

[0005] Typically, and more typically for those performing home testing protocols, common sampling sites include the fingers. Recently however, the arm has become a popular alternative sampling site because its nerve beds are sparser than in the fingers, thus minimizing pain somewhat. However, collecting a physiological fluid sample from the arm has disadvantages as well. Most notably, there are particular anatomical and physiological aspects of the arm which make physiological fluid collection from it difficult.

[0006] Small veins and arteries typically reach to within about 1 mm of the surface of the skin; arterioles ascend vertically from these to within about 0.5 mm of the surface where they branch out and become capillaries which reach to within about 0.25 mm of the surface. The capillaries terminate in venuoles which carry blood back to veins. Each ascending arteriole feeds a maze of branched arterioles, capillaries and venuoles, where each groupings of capillaries, venuoles and arterioles have horizontal dimensions on the order of about 2-7 mm. Skin piercing to obtain blood from these structures is usually done to a depth of about 1 mm or less. Spaces exist between these areas where the arterioles, venuoles and capillaries are non-existent, sparse or not sufficiently engorged with blood.

[0007] When randomly choosing a sampling site, a patient may encounter a substantially high fluid flow area or a substantially low fluid flow area. Oftentimes, an adequate or minimum volume of sample is required in order to perform a particular test accurately. Thus, if such a minimum volume were not collected from a first skin piercing, the patient would be required to continually pierce the skin until the minimum volume were

obtained. It can be appreciated that this process of multiple skin piercings would contribute to more pain to the patient.

[0008] Furthermore, certain tests require a particular sample type in order to perform an accurate test. However, when randomly choosing a site to pierce the skin, a patient may encounter (1) a region with substantially few or no arteries or veins, and thus a good source of interstitial fluid, but not a good source of arterial or venous blood, (2) a region rich in arteries and thus a good source of arterial blood, but not a good source of venous blood or interstitial fluid, (3) a region rich in veins and thus a good source of venous blood, but not a good source of arterial blood or interstitial fluid, and (4) a combination of 1-3 which may not be suitable for any test. Blood from capillaries tends to be arterial in nature. Thus, if sample is ultimately obtained from a site such as site (1) above for a test which requires a blood sample, *i.e.*, a site with few or no sources of arterial or venous blood, the sample may be diluted with or composed entirely of interstitial fluid which may skew results of the particular test. For instance, it is known that arterial samples, venous samples and interstitial fluid samples may have different analyte concentrations, *e.g.*, arterial blood can have as much as 7 mg/dl higher glucose levels than does venous blood. Thus, it can be appreciated that the ability to choose a suitable sampling site is very important. Furthermore, if a type of sample is obtained that is not appropriate for a particular testing protocol, the patient may be required to pierce the skin additional times, again contributing more pain to the patient.

[0009] As such, there is continued interest in the development of new devices and methods for use for non-invasively determining whether, once the skin is pierced, the patient will be able to obtain the appropriate sample volume from the site for the particular test to be performed and also whether an appropriate sample type can be obtained from the site. Of particular interest would be the development of such devices, and methods of use thereof, which are efficient and simple to use. Such devices integrated with at least one skin-piercing element for piercing the skin once an appropriate sampling site has been non-invasively determined and/or integrated with a reagent test strip for determining the concentration of an analyte in the sample would also be of particular interest.